



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

FEB 29 2000

2075 '00 MAR -1 P1:55

The Honorable Gordon H. Smith  
United States Senator  
One World Trade Center  
121 S.W. Salmon  
Suite 1250  
Portland, Oregon 97204

Dear Senator Smith:

Thank you for your letter of August 25, 1999, on behalf of Ms. Nicole Britton of Aumsville, Oregon. We regret our delay in responding. Ms. Britton's child has a condition, celiac sprue, which causes an intolerance to the protein component of the gluten in wheat, barley, rye, and oats. This means her child needs to avoid food products containing these grains. Ms. Britton is concerned about "hidden" gluten in products labeled as having "natural" or "artificial" flavorings.

By way of background, the Federal Food, Drug, and Cosmetic (FD&C) Act requires that all foods fabricated from two or more ingredients must declare each ingredient by its common or usual name in the ingredient statement in descending order of predominance by weight. The FD&C Act provides two narrow exemptions from ingredient labeling requirements. The first one provides that spices, flavorings, and certain colorings may be declared collectively without naming each one. The second one provides that incidental additives, such as processing aids that are present at insignificant levels and do not have a functional effect in the finished food, do not have to be declared on the label.

Staff at the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) have been considering whether to revise the regulation regarding natural flavorings to make it more user friendly and to make it more meaningful to consumers. We have forwarded your correspondence to our staff at CFSAN for their consideration.

99P-2148

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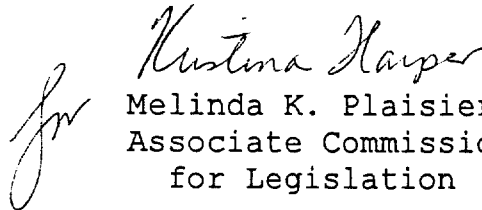
1/2/18

In addition, we have recently received a citizen petition raising concerns similar to those raised in your letter and requesting FDA to amend its food labeling regulations to require the specific ingredient listing of spices and natural and artificial flavoring on the label. We have forwarded your correspondence to the docket for this matter for inclusion in the record. Please be assured that we will consider all comments before making a final decision on this issue.

FDA understands the difficulties faced by persons with food allergies and intolerances. We appreciate Ms. Britton's comments. We have enclosed an article from FDA Consumer magazine, "The New Food Label: Better Information for Special Diets," that may be of interest to her.

We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,

  
Melinda K. Plaisier  
Associate Commissioner  
for Legislation

Enclosure

cc: Dockets Management Branch  
(#99P-2148/CP)

# United States Senate

WASHINGTON, DC 20510-3704

August 25, 1999

Ms. Diane Thompson  
Associate Commissioner for Legislative Affairs  
Food and Drug Administration  
U.S. Department of Health and Human Services  
Parklawn Building - 5600 Fishers Lane, Rm 15-55  
Rockville, MD 20857

Dear Ms. Thompson:

Enclosed please find a copy of correspondence I recently received from Ms. Nicole Britton regarding food labeling for gluten content.

In an effort to provide this individual with an appropriate response, I would appreciate your comments on the issues raised in this letter. I look forward to a reply at my Portland office at One World Trade Center, 121 SW Salmon, Suite 1250, Portland, Oregon 97204.

Thank you in advance for your kind attention to this inquiry.

Sincerely,



Gordon H. Smith  
United States Senator

GS:jr  
Enclosure

cc: Ms. Nicole Britton  
10774 Mill Creek Road  
Aumsville, Oregon 97325

Ms. Janet Rinehart  
President  
Celiac Sprue Association  
PO Box 31700  
Omaha, NE 68131

*No. 99-5669*

JR

Author: mcr@wvi.com at Internet  
Date: 8/19/99 7:58 PM  
Subject: food ingredients information disclosure  
----- Message Contents

FROM:

NAME: Nicole Britton  
ADDRESS: 10774 mill creek rd  
aumsville, OR 97325

Senator Smith:

I am sending this letter to Rep. Darlene Hooley Sen. Gordon Smith Sen. Ron Wyden

It is my hope that one of you will be able to steer me in the right direction with my situation.

I have a 2 1/2 year old with a disease; called celiac spruce. There is no cure for this disease...little money is funded to research this disease because it can be treated with a diet (like a diabetic). In my son's case he cannot have gluten (this is found in wheat, oats, rye, millet, malt, barley).

If a person with my sons disease digest gluten; they have a reaction; the lining in there bowels is damaged...they suffer pain, bloating, Dermatitis Herpetiformis(a skin rash the body creates in an attempt to get rid of the toxins),and some times nausea for a few days. Additionally; their body will not be able to properly digest needed nutrients for a period of time. The damage that happens to their intestines over the course of time has a great potential to develop cancer...further more a gut that is continually exposed to gluten can become "leaky" this can be fatal. My son has been on a gluten free diet since he was 11 months.

I am thankful for the fact that his disease can be controlled with a simple diet...but I am frustrated with sloothing out the hidden gluten in various products. Gluten is often "hidden" in a products label as "natural and or artificial flavorings", "natural and or seasonings", preservatives..ect. I am forced to contact each company ( after I read through the label and think it may be okay). My frustration is when I contact the companies most of them are very much aware of the gluten content of their products....but don't see the need to put the gluten status on the label. I recently spent a whole afternoon trying to find out what bands of mustard my son could have. Most companies wont give me a

straight  
answer over the phone and want to mail me an answer....so as always...I wait  
for the  
answe~~r~~e to come in the mail.....on their brochure that they have all made  
up.....and I  
..and 1000's other celiacs (or parents of celiacs) are at there mercy....

I would like to see this change. There is a significantly larger # of diabetics  
in the united  
states than celiacs.... hence they have had more funding and more legislation.  
I am aware  
that food labels must disclose any content of sugar( for the sake of the  
diabetic)....It is my  
hope that the same can be done for the gluten content. It is my hope that one of  
you will  
respond to my letter with some suggestions on how to initiate the process of  
have gluten  
content disclose on ingredients labels.

If any of you want to educate yourselves on this disease here is info on an  
excellent place  
to start. Celiac Sprue Association            P.O. Box 31700      Omaha, NE 68131-0700  
Tel:  
(402) 558-0600      The President: Janet Rinehart      Tel: (713) 783-7608  
E-mail:  
76131.2257@compuserve.com      Internet: [http://www.csaceliacs.org/thank you so  
much](http://www.csaceliacs.org/thank%20you%20so%20much)  
for your time; any help would be greatly appreciated.

thank you for your time  
Nicole Britton  
10774 mill creek rd  
aumsville or 97325